CLAIMS

1. A method for preparing a sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, with a very fast bioresorption rate, said SiO_2 optionally comprising a specific percentage or percentages of a biologically active agent or agents other than the SiO_2 itself with or without protective agent or agents for said biologically active agent or agents, wherein method a sol-gel derived SiO_2 is prepared from a sol comprising water, an alkoxide or inorganic silicate and a lower alcohol, i.e. an alcohol with ≤ 4 carbons, using a mineral acid or a base as a catalyst, preferably a mineral acid, and said sol is aged and dried **characterised** in that

a) in the sol the starting
   i) pH is from 0.05 to 2.5, preferably 1.5 to 2.5, most preferably 2.0,
   ii) molar ratio of water to the alkoxide or inorganic silicate is 0.5 to 2.5; preferably 1.5 to 2.5,
   iii) molar ratio of alcohol to the alkoxide or inorganic silicate is ≥ 0.5, preferably ≥ 1.0; and

b) either,
   i) the sol is, without induced changes of sol composition,
      - let to gel spontaneously at a temperature of ≤ 25 °C or an elevated temperature of 65 °C to 90 °C , preferably at an elevated temperature of 65 °C to 90 °C, or
      - gelation of the sol is done by forced drying of the sol, or

   ii) a change or changes of sol composition are induced after sol ageing but before gel formation, said change or changes of sol composition optionally comprising addition of said biologically active agent or agents with or without said protective agent or agents, and

   the ratio t/t_{gel} is ≥ 0.005, preferably ≥ 0.1, most preferably ≥ 0.9, wherein

t is the ageing time of the sol, i.e. time from preparation of said sol to the induced changes, and

t_{gel} is the time point where the sol would have turned to a gel without the induced changes; and

forced drying of the sol is carried out or initiated within a time of ≤ 30 minutes, preferably ≤ 15 minutes, most preferably ≤ 5 minutes, from said induced change or changes.

2. A method for adjusting the bioresorption rate of sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, optionally comprising a specific percentage or percentages of a biologically active agent or agents other than the SiO_2 itself with or without protective agent or agents for said biologically active agent or agents, **characterised** in that

A) a SiO_2 with a very fast bioresorption rate is obtained according to the method of preparing a SiO_2 of claim 1; and

B) a SiO_2 with a slower bioresorption rate than the very fast bioresorption rate is obtained by correlating a desired biodegradability of a SiO_2 with changes a), b) and/or c) to the method of preparing a SiO_2 according to claim 1, wherein

a) comprises deviating in the sol any of the starting values:

i) pH,

ii) molar ratio of water to the alkoxide or inorganic silicate, and/or

iii) molar ratio of alcohol to the alkoxide or inorganic silicate;

from the values defined in a) i) – iii) of claim 1;

b) comprises carrying out induced changes by addition of a component or components, including optional addition of the biologically active agent or agents with or without said protective

agent or agents, said changes affecting any of the values i) – iii) of a) of claim 1 or a) if applied by

i) not carrying out forced drying, or

ii) carrying out or initiating forced drying of the sol later than defined in b) ii) of claim 1; and

c) comprises deviating the temperature for letting the sol gel spontaneously from the values defined in b) i) of claim 1; and

a method for preparing the SiO_2 with said changes to the method correlating with the desired biodegradability is carried out for obtaining the SiO_2 with the desired slower biodegradability.

3. The method according to claim 2 **characterised** in that an alkoxide, preferably tetraethoxysilane (TEOS), is used for preparing the sol-gel derived SiO_2.

4. The method according to claim 2 or 3 **characterised** in that that an inorganic silicate, preferably sodium or potassium silicate, is used for preparing the sol-gel derived SiO_2.

5. The method according to any of claims 2 to 4 **characterised** in that the lower alcohol is ethanol.

6. The method according to any of claims 2 to 5 **characterised** in that the induced change is selected from the group consisting of adding water, adding the alkoxide or inorganic silicate, adding the alcohol, adjusting pH by adding an acid or base, preferably the acid or base used as the catalyst, adding the optional bioactive agent or agents with or without protective agent or agents for said biologically active agent or agents affecting any of the values i) – iii) of a) in claim 1 or a) of claim 2 if applied, and any combination thereof.

7. The method according to any of claims 2 to 6 **characterised** in that drying of the sol is drying by ambient heat, vacuum drying, electromagnetic drying,

acoustic drying, spray-drying or freeze-drying, preferably spray-drying or freeze-drying.

8. The method according to any of claims 2 to 7 **characterised** in that forced drying of the sol is carried out, preferably by spray-drying or freeze-drying.

9. The method according to claim 8 **characterised** in that forced drying is freeze-drying initiated by freezing the sol.

10. The method according to claim 8 or 9 **characterised** in that the temperature of the sol is ≤ +90 °C, preferably ≤ +50 °C, most preferably ≤ +40 °C.

11. The method according to any of claims 2 to 10 **characterised** in that the gel is dried.

12. The method according to claim 11 **characterised** in that drying of the gel is drying by ambient heat, vacuum drying, electromagnetic drying, acoustic drying, spray-drying or freeze-drying, preferably ambient heat or freeze-drying.

13. The method according to claim 11 or 12 **characterised** in that the gel is dried at a temperature of ≤ 700 °C, preferably ≤ 50 °C, and most preferably ≤ 40 °C.

14. The method according to any of claims 2 to 13 **characterised** in that a value to be deviated to obtain a slower bioresorption rate is the ratio of water to the alkoxide or inorganic silicate, and the more the ratio of water to alkoxide or inorganic silicate is deviated to be higher or lower the slower the bioresorption rate obtained.

15. The method according to any of claims 2 to 14 **characterised** in that a value to be deviated to obtain a slower bioresorption rate is the ratio of alcohol to

the alkoxide or inorganic silicate, and the more the ratio is deviated to be higher or lower the slower the bioresorption rate obtained.

16. The method according to any of claims 2 to 15 **characterised** in that a value to be deviated to obtain a slower bioresorption rate is the pH, and the more the pH is deviated to be higher or lower the slower the bioresorption rate obtained.

17. The method according to any of claims 2 to 16 **characterised** in that a biologically active agent or agents is added to the sol before gel formation.

18. The method according to any of claims 2 to 17 **characterised** in that any of the values pH, molar ratio of water to the alkoxide or inorganic silicate, and/or molar ratio of alcohol to the alkoxide or inorganic silicate is changed to deviate from the ranges defined in claim 1, a) i) – iii), after sol ageing but before gel formation and/or optional addition of said biologically active agent or agents, and within ≤ 30 minutes, preferably ≤ 15 minutes and most preferably ≤ 5 minutes from the change forced drying of the sol is carried out or initiated.

19. The method according to any of claims 2 to 18 **characterised** in that the biologically active agent or agents is selected from the group consisting of a drug, peptide, protein, hormone, growth factor, enzyme, polysaccharide, living or dead cells or viruses or parts thereof, plasmids, polynucleotides, water soluble ions, salts and any combination thereof.

20. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

21. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.35 wt-%/h.

22. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a coating, preferably with a thickness of < 0.5 mm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

23. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a coating, preferably with a thickness of < 0.5 mm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

24. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

25. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.5 wt-%/h.

26. The SiO_2 according to any of claims 20, 22, 23 and 24, **characterised** in that the dissolution rate of the SiO_2 is ≥ 0.30 wt-%/h.

27. The SiO_2 according to claim 21 or 26, **characterised** in that the dissolution rate of the SiO_2 is ≥ 0.5 wt-%/h preferably ≥ 1.0 wt-%/h, more preferably ≥ 2.0 wt-%/h and most preferably ≥ 4.0 wt-%/h.

28. A bioresorbable sol-gel derivedSiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.15 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

29. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.06 wt-%/h, preferably from 0.002 to 0.05 wt-%/h, and from 0.006 to 0.025 wt-%/h.

30. The SiO_2 according to claim 22 or 23 **characterised** in that the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.15 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

31. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.008, and preferably from 0.002 to 0.003 wt-%/h.

32. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.10 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

33. A bioresorbable sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, obtainable according to the

method of any of claims 2 to 19, wherein said SiO_2 comprises a biologically active agent other than the SiO_2 itself and said biologically active agent is a peptide, protein or cell, **characterised** in that the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

34. A bioresorbable sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, obtainable according to the method of any of claims 2 to 19, wherein said SiO_2 comprises a biologically active agent other than the SiO_2 itself and said biologically active agent is a peptide, protein or cell, **characterised** in that the dissolution rate of the SiO_2 is ≥ 0.5 wt-%/h and preferably ≥ 4.0 wt-%/h.

35. A bioresorbable sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, obtainable according to the method of any of claims 2 to 19, wherein said SiO_2 comprises a biologically active agent other than the SiO_2 itself and said biologically active agent is a peptide, protein or cell, **characterised** in that the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.15 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

36. Use of a bioresorbable sol-gel derived SiO_2 according to any of claims 20 to 35 for administering a biologically active agent to a human or animal body, wherein said use comprises administering selected from the group consisting of oral, buccal, rectal, parenteral, pulmonary, nasal, ocular, intrauterine, vaginal, urethral, topical, transdermal and surgically implantable administering.

37. Use of a bioresorbable sol-gel derived SiO_2 according to any of claims 20 to 35 for administering a biologically active agent to a plant.